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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,228	11/12/2003	Maria da Graca Henriques Vicente	0210.1 Vicente	8492

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PATENT DEPARTMENT
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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
07/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,228	VICENTE ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *6,10,11,17,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,12-16,18-20 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on 5/21/2007. Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the ground(s) that it is improper to restrict a claim against itself and that the two groups are related. This is not found persuasive because it is proper to restrict within a single claim if it is claiming a wide variety of any and all viral infections that are patentable distinct. Furthermore, the two groups are unrelated because a search for HIV will not lead to information regarding viral infections other than HIV in the non-patent literature. The requirement is still deemed proper and is therefore made FINAL. Claim(s) 1-23 are pending. Claim(s) 6, 10-11, 17, 21-22 are withdrawn from further consideration as being drawn to a non-elected species. Claim(s) 1-5, 7-9, 12-16, 18-20, 23 are examined herein insofar as they read on the elected invention and species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9, 12-16, 18-20, 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the treatment of HIV infection in a patient by administering a porphyrin macrocycle comprising one or more

carboranyl groups, does not reasonably provide enablement for *preventing*. The specification does not enable any person skilled in the art to which it pertains to practice the invention commensurate in scope with these claims. Examiner notes that the term "inhibition" will be interpreted as "prevention" for examination purposes.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention which pertains to a method of treating and preventing viral infections in a patient by administering a porphyrin macrocycle comprising one or more carboranyl groups.

(2) State of the Prior Art: The state of the art regarding treating viral infection is relatively high, however the state of the art for the prevention of viral infection, especially HIV is non-existent.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the prevention, inhibition, and treatment of every known viral infection.

(4) Guidance of the Specification: The guidance of the specification as to the prevention of viral infections is completely lacking. The specification discloses preventing the onset of viral infections. However, the specification fails to mention how one is able to determine whether the onset of viral infections in a subject would have occurred in the absence of treatment, thus being unable to confirm that prevention has indeed taken place. Moreover, the specification fails to mention the complete prevention or cessation of viral infections once the onset of preclinically evident stage is determined.

(5) The Predictability or Unpredictability of the Art: The invention is directed to a method of treating, inhibiting, and preventing every known viral infection. The specification does not disclose how one of ordinary skill in the art at the time of the invention would be able to prevent viral infections, nor does the prior art reveal any type of prevention associated with viral infections.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to prevent viral infections. Moreover, one is unable to determine whether a subject will ever develop a viral infections should this subject be administered a porphyrin macrocycle comprising one or more carboranyl groups.

(7) Working Examples: The specification does not give any data for the prevention of viral infections. The only working example given is treatment of HIV infection in vitro.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the prevention of viral infections. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claims 1-5, 7-9, 12-16, 18-20, 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of HIV infection, does not reasonably provide enablement for treatment of all types of viral infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7)

the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention, which pertains to a treatment, inhibition, and prevention of every known type of viral infection.

(2) State of the Prior Art: The state of the art regarding treatment of viral infections is moderate depending on the virus.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass treatment for every known type of viral infection.

(4) Guidance of the Specification: The guidance of the specification as to the treatment of viral infections is limited to HIV.

(5) The Predictability or Unpredictability of the Art: The invention is directed to treatment of every known viral infection. The correlation between different types of viruses is unpredictable considering different mechanism of action of the virus. Each virus presents its own unique set of symptoms.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to treat every known viral infection.

(7) Working Examples: The specification gives only one working example limited to HIV treatment.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the treatment of all known viral infections. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at

1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-12, 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what exactly is the structure of compounds 4, 6, 10, 12, 16, 18, 22, 24, 31, and 33 since the claims do not contain any structures or formulas associated with these specific compounds.

Claims 8 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "light having a wavelength, intensity, and duration sufficient to significantly enhance the compound's inhibition and prevention of viral infection" renders the claim indefinite as to what types of light are sufficient to significantly enhance the compound's inhibition and prevention of viral infection. The specification does not define light that is sufficient to significantly enhance the

compound's inhibition and prevention of viral infection. Therefore, the metes and bounds of patent protection sought for the instant claims have not been defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1-5, 7-9, 12-16, 18-20, 23 are rejected under 35 U.S.C. 103(a) as being obvious over Debnath et al. ("Anti-HIV-1 activity of carborane derivatives of porphyrins," *Med. Chem. Res.*, vol. 9, pp. 267-273, 1999, of record) in view of Vicente et al. (WO 01/85736 A1, of record).

The instant claims are directed to a method of preventing or treating HIV infection by administering to a patient a porphyrin macrocycle comprising one or more carboranyl

groups as depicted by compound 33 (Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt).

Debnath teach carborane derivatives of porphyrins, originally designed as boron neutron capture agents, also possess anti-HIV activity (title and abstract). Table 1 lists some examples of boronated porphyrins.

However, Debnath fail to specifically disclose compound 33.

Vicente teach carbon-carbon linked carboranyl-containing porphyrins as neutron capture agents for cancer therapy (title and abstract). A preferred compound is Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt (pg. 25). These porphyrins are used in boron neutron capture therapy for cancer treatment, which includes irradiation by red light (claim 27-29).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have used the boron neutron capture therapy on a HIV infected patient by administering compound 33.

A person of ordinary skill in the art would have been motivated to use boron neutron capture therapy on a HIV infected patient by administering compound 33 because: (1) both Debnath and Vicente disclose boron neutron capture therapy; (2) both Debnath and Vicente disclose carbon-carbon linked carboranyl-containing porphyrins as neutron capture agents; (3) of the functional art equivalence of the porphyrins disclosed by Debnath and compound 33 disclosed by Vicente; and (4) Debnath teach carborane derivatives of porphyrins possess anti-HIV activity. Therefore, the skilled artisan would have had a reasonable expectation of success in

treating HIV infection in a patient by administering Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt or compound 33.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER